

FCS13 – SOP for Proficiency Testing

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1. Scope

- 1.1. These procedures apply to analytical or interpretive procedures on evidentiary items. Open proficiency tests are analyzed and interpreted according to the unit's approved protocols in use at the time of the proficiency test.

Note: Proficiency tests are expected to be completed as one would complete assigned casework. However, assigned casework does at times entail the discussion of one's work amongst their supervisor(s) as well as peers or selection of appropriate and available laboratory tests. During proficiency testing, it is expected that individuals testing during the assigned round of proficiency testing shall limit their discussion of the test to direct supervisors and Technical Leaders and not with those also in the assigned round of proficiency testing. Additionally, individuals may not deviate from the specifically assigned tests/methodologies without prior approval from the Unit Manager, Technical Leader or designee. Failure to do so can subject the individual to corrective action as defined by DOM07 – Practices for Quality Corrective Action and/or disciplinary action as defined by the DPM of the District of Columbia Human Resources.

2. Background

- 2.1. The open proficiency testing procedures are a measure used by the Department of Forensic Sciences (DFS) Public Health Laboratory (PHL) Forensic Chemistry Unit (FCU) to monitor the continued technical proficiency of FCU personnel documented as competent in a particular forensic science discipline. These

procedures are designed to demonstrate the FCU personnel performing forensic examinations produce reliable work and analytical procedures are conducted within the established performance criteria. The program is designed in a manner to test analysts as well as the FCU quality system. These procedures also satisfy the requirements of the *FCU Quality Assurance Manual*, the accreditation standards under ISO/IEC 17025 (current revision), and applicable supplemental standards.

3. Safety

- 3.1. Read Material Safety Data Sheets to determine the safety hazards for chemicals and reagents used in the standard operating procedures.
- 3.2. Wear personal protective equipment (e.g., lab coat, gloves, eye protection), when carrying out standard operating procedures.

4. Materials Required

- 4.1. See *FCS01 – SOP for Detecting Controlled Dangerous Substances*.

5. Standards and Controls

- 5.1. See *FCS01 – SOP for Detecting Controlled Dangerous Substances*.

6. Calibration

- 6.1. As required to perform analysis. See FCU Standard Operating Procedures (current revisions) for instrument maintenance and/or performance check procedures.

7. Procedures

- 7.1. The laboratory shall participate annually in at least one external proficiency test for each discipline of forensic science in which it provides services. ISO/IEC 17043 accredited proficiency test providers shall be used where available. Whenever there is not an ISO/IEC 17043 accredited proficiency test provider available, the laboratory shall locate and use a proficiency test provider who offers an external test in that discipline.

Note: If an external provider is not available for a particular test, an internally designed and prepared test will meet the annual proficiency testing requirement.

- 7.2. Each analyst must complete at least one open proficiency test annually. The test may be external or internal and will test his/her capabilities and performance in

each discipline or sub-discipline in which he/she routinely performs casework. Each person tested must participate in the test to the extent that he/she would perform the procedures in casework.

7.2.1. Prior to test data being returned to the test provider, technical and administrative reviews must be performed.

7.2.2. The date the proficiency test is assigned is the date that is referred to when determining subsequent proficiency test assignment dates.

7.3. Proficiency Test Procedures

7.3.1. Proficiency tests are intended to monitor work as normally performed in the laboratory and are to be conducted using the currently approved casework procedures. Work is to be done independently by the analyst, supported by notes, photographs and other documentation, and summarized in a written report as required by casework. Prior to reporting the proficiency test results to the proficiency test provider, the work is to receive the same level of technical and administrative review required for casework. Individuals in the same round of proficiency testing for a specific discipline should not perform technical reviews of their colleague's work unless their own proficiency test has undergone a technical review.

7.4. Proficiency Test Evaluation

7.4.1. The Unit Manager or designee will review the results and supporting documentation and compare the submitted results with the expected results. An evaluation form will be completed for each proficiency test administered. The form will be completed when the proficiency test results are evaluated for an internal test. The form will be completed after the manufacturer's results are received for an external test. The evaluation form will include, at a minimum:

7.4.1.1. Name of test participant and title

7.4.1.2. Discipline

7.4.1.3. Test provider

7.4.1.4. Test identification number

7.4.1.5. Provider due date

7.4.1.6. Date assigned

7.4.1.7. Completion date

7.4.1.8. Name of reviewer and the review date

7.4.1.9. Results: satisfactory or unsatisfactory

7.4.1.10. Description of discrepancy(ies) or corrective action(s), when appropriate.

7.4.2. Upon completion, the evaluation form will be made available to the test participant. Each test participant must document his/her receipt of the test evaluation.

7.4.2.1. If a test participant chooses not to sign the form, the unit manager or designee will document the meeting on the evaluation form.

7.5. Proficiency Test Records

7.5.1. The Deputy Director will ensure the maintenance of records of proficiency tests. These records include:

7.5.1.1. Test identification number

7.5.1.2. Method used to obtain or create samples

7.5.1.3. Name of the test participant

7.5.1.4. Date of analysis and completion

7.5.1.5. Original copies of all data and notes supporting the conclusions

7.5.1.6. The proficiency test results

7.5.1.7. Any discrepancies noted

7.5.1.8. The proficiency test evaluation form including analyst feedback

7.5.1.9. Details of corrective action (if necessary)

7.6. Corrective Action

7.6.1. During the review process, administrative and technical errors will be brought directly to the attention of the test participant by the reviewers. All errors found during the review will be corrected prior to the completion.

7.6.2. Analytical and/or interpretive errors, found before or after proficiency test submittal, will be reviewed to determine if the error is an employee performance issue. The Unit Manager or designee will document the error, notify the test participant of the error, and record the date of the notification on the technical or administrative review sheet if found before submittal, or on the Proficiency Test Evaluation Form, if found after submittal. At the discretion of the Unit Manager or designee, the test participant may address the error and complete the proficiency test.

7.6.2.1. If the error is an employee performance issue, it will be addressed by the Technical Leader or designee and will not require a Q-CAR.

7.6.2.2. If the nonconformity rises to the level of a Q-CAR in frequency or impact, the Technical Leader or designee will determine the root cause of the error and a Q-CAR will be issued. The analyst will be removed from casework until the corrective action has been resolved. Depending on the nature of the error, an audit of casework completed by the analyst since his/her last satisfactory proficiency test may be required. Before resuming casework, the analyst must complete remedial training and satisfactorily complete a proficiency test (or competency test).

7.6.2.2.1. The vendor's statistical report may be consulted to determine the validity of the test results and if the test was an adequate representation of expected results.

7.6.2.2.2. The Technical Leader or designee may also review the proficiency test samples, if available, to resolve if the analyst made a technical error and should be removed from casework.

7.7. If the error is determined to be the result of a systemic problem (e.g., equipment, materials, environment, etc.), an audit of all cases completed since the laboratory's last satisfactory proficiency test may be required. Depending on the nature of the error, casework analysis may be suspended until the cause of the error is identified and corrected. The Technical Leader or designee will determine the root cause of the error and a Q-CAR will be issued. All affected analysts will be informed of the corrective action.

7.8. Blind Testing

7.8.1. Blind testing may be performed in addition to any external proficiency testing requirements.

- 7.8.2. Blind tests can be internally or externally produced.
- 7.8.3. Blind tests will be introduced as case work.
- 7.8.4. Tests will be reviewed using the same guidelines as previously stated for proficiency testing.
- 7.8.5. Tests will be for internal review only and will not be used to meet external accreditation requirements or standards.

8. Sampling

- 8.1. See *FCS01 – SOP for Detecting Controlled Dangerous substances* and *FCS02 – SOP for General Laboratory Procedures for FCU*

9. Calculations

- 9.1. All calculations will be recorded in the case notes with appropriate uncertainty provided.

10. Uncertainty of Measurement

- 10.1. See *FCS21 – Procedure for Uncertainty in Measurement*.

11. Limitations

- 11.1. See specific method SOP for limitations on analytical processes.
- 11.2. Limitations must be clearly conveyed within the laboratory report.

12. Documentation

- 12.1. FCU Examination Worksheets
- 12.2. FCU Laboratory Report
- 12.3. The following records will be generated and retained for at least one accreditation cycle or five years, whichever is longer:
 - 12.3.1. Proficiency Test Records
 - 12.3.2. Q-CAR with associated responses (if applicable)

13. References

- 13.1. ISO/ IEC 17025 (current revision) – General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland.
- 13.2. ANAB Supplemental Requirements for Forensic Testing, ANSI-ASQ National Accreditation Board, Milwaukee, WI, (current revision).
- 13.3. DFS Departmental Operations Manuals, (current revisions).
- 13.4. Forensic Chemistry Unit Quality Assurance Manual, (current revisions)
- 13.5. Forensic Chemistry Unit SOPs, (current revisions).